4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0097]

Draft Guidance for Industry on Providing Submissions in Electronic Format--Standardized Study Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Submissions in Electronic Format--Standardized Study Data." This draft guidance establishes FDA's recommendation that sponsors and applicants submit nonclinical and clinical study data in a standardized electronic format. The draft guidance recognizes that standardized study data promotes the efficient review of this information. The purpose of this draft guidance is to promote the use of data standards for study data, and increase the number of standardized study data submissions to the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Submissions in Electronic Format--Standardized Study Data." FDA routinely receives submissions of the results of scientific studies, including clinical trials and animal studies. For many years, FDA has requested that clinical study data be submitted electronically because paper case report tabulations (CRTs) are universally recognized as being highly inefficient to support analysis and review. The data in paper CRTs are not machine-readable and therefore cannot be easily analyzed using modern analytic software. Although submission of clinical study data in electronic format has become relatively routine, these data are often submitted using nonstandard formats.

FDA has long recognized the advantage of standardizing study data, as have many sponsors and applicants. Data submitted in a standard electronic format are easier to understand, analyze, and review.

This draft guidance establishes FDA's recommendation that sponsors and applicants submit clinical and nonclinical study data in a standard electronic format. As sponsors and applicants move toward standardized electronic study data submissions, there is a need to understand FDA's expectations for such data submissions. This draft guidance provides FDA's current thinking on the submission of study data in a standard electronic format.

The draft guidance refers submitters to FDA's Study Data Standards Resource Web page at http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm, where there is useful information describing which data standards to use and how to use them.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on submitting standardized study data in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 314 and 21 CFR part 312 have been approved under OMB control numbers 0910-0001 and 0910-0014, respectively. The collections of information in 21 CFR part 807, subpart E have been approved under 0910-0120; the collections of information in 21 CFR part 812 have been approved under 0910-0078; and the collections of information in 21 CFR part 814 have been approved under 0910-0231.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: February 14, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-3956 Filed 02/17/2012 at 8:45 am; Publication Date: 02/21/2012]